torney Docket No.: 125889.101 PATENT

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Fetterman et al.

Serial No.

10/722,262

: Group Art Unit: 1616

Filed:

November 25, 2003

Examiner: Not Yet Assigned

For: METHOD OF ASSESSING AND MANAGING RISKS ASSOCIATED

WITH A PHARMACEUTICAL PRODUCT

## INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents Mail Stop DD P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

In accordance with the provisions of 37 C.F.R. 1.56, 1.97 and 1.98, the attention of the Patent and Trademark Office is hereby directed to the documents listed on the attached form PTO-1449. Copies are provided. It is respectfully requested that the documents be expressly considered and that the documents be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

It is respectfully requested that the references be expressly considered during the prosecution of this application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

## **AUTHORIZATION**

No fee is required. The Commissioner is hereby authorized to charge any additional fees which may be required for this submission, or credit any overpayment to deposit account no. 50-0436.

Respectfully submitted,

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Date: April 14, 2004

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Complete if Known itute for form 1449/PTO **Application Number** 10/722,262 Filing Date November 25, 2003 INFORMATION DISCLOSURE STATEMENT BY APPLICANT First Named Inventor Fetterman Group Art Unit 1616 (use as many sheets as necessary) **Examiner Name** Not yet assigned Sheet 125889.101 Attorney Docket Number **U.S. PATENT DOCUMENTS** Examiner's Cite U.S. Patent Document Name of Patentee or Applicant of Date of Pages, Columns, Lines, Where Initials Cited Document Publication of No. Relevant Passages or Relevant Cited Document Figures Appear Number Kind Code MM-DD-YYYY (if known) FOREIGN PATENT DOCUMENTS Examiner's Cite Foreign Patent Document Name of Patentee or Applicant of Date of Pages, Columns, Lines, Initials Cited Document Publication of Where Relevant Passages Cited Document or Relevant Figures Appear Office Number Kind Code MM-DD-YYYY (if known) OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.) Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, Examiner's Cite Initials No. magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or county where published. White Paper: Supporting National Treatment Practice Guidelines by Combining CME Program and Process of Care™ CA DeRosier, Joseph; Stalhandske, Erik; Bagian, James P.; Nudell, Tina. "Using Health Care Failure Mode and Effect CB Analysis™: The VA National Center for Patient Safety's Prospective Risk Analysis System"; The Joint Commission May 2002 Journal.

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

## **CERTIFICATE OF MAILING UNDER 37 C.F.R. § 1.10**

APPLICANT:

Fetterman et al.

TITLE:

METHOD OF ASSESSING AND MANAGING RISKS

ASSOCIATED WITH A PHARMACEUTICAL PRODUCT

SERIAL NO.

10/722,262

**ATTORNEY REF:** 

125889.101

**DATE OF DEPOSIT:** 

April 14, 2004

I HEREBY CERTIFY THAT THIS INFORMATION DISCLOSURE STATEMENT WITH COPIES OF REFERENCES CITED THEREIN IS BEING DEPOSITED WITH THE UNITED STATES POSTAL SERVICE VIA FIRST CLASS MAIL UNDER 37 CFR 1.10 ON THE DATE INDICATED ABOVE AND IS ADDRESSED TO COMMISSIONER FOR PATENTS, MAIL STOP DD, P.O. BOX 1450, ALEXANDRIA, VA 22313-1450.

Jennifer Martinez

(Typed or printed name of person mailing paper or fee)

Documents Enclosed:

1. Information Disclosure Statement with cited references;

2. Certificate of Mailing;

3. Postcard